the telephone number for the Air Docket Center is (202) 566–1741.

In addition to being available in the docket, an electronic copy of this **Federal Register** notice is also available on the World Wide Web at *http://www.epa.gov/climatechange/emissions/ghgrulemaking.html.*

List of Subjects in 40 CFR Part 98

Environmental Protection, Administrative practice and procedures, Air pollution control, Monitoring, Reporting and recordkeeping.

Dated: June 15, 2011.

Lisa P. Jackson,

Administrator.

For the reasons discussed in the preamble, title 40, chapter I, of the Code of Federal Regulations is amended as follows:

PART 98—[AMENDED]

■ 1. The authority citation for part 98 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart I—[Amended]

■ 2. Section 98.94 is amended as follows:

■ a. By revising paragraph (a)(1) introductory text.

■ b. By revising paragraph (a)(3) introductory text.

■ c. By revising paragraph (a)(3)(i).

■ d. By revising paragraph (a)(4)(i).

§ 98.94 Monitoring and QA/QC requirements.

(a) * * *

(1) *Best available monitoring methods.* From January 1, 2011 through September 30, 2011, owners or operators may use best available monitoring methods for any parameter that cannot reasonably be measured according to the monitoring and QA/QC requirements of this subpart. The owner or operator must use the calculation methodologies and equations in § 98.93, but may use the best available monitoring method for any parameter for which it is not reasonably feasible to acquire, install, or operate a required piece of monitoring equipment in a facility, or to procure necessary measurement services by January 1, 2011. Starting no later than October 1, 2011, the owner or operator must discontinue using best available monitoring methods and begin following all applicable monitoring and QA/QC requirements of this part, except as provided in paragraphs (a)(2), (a)(3), or (a)(4) of this section. Best available monitoring methods means any of the following methods specified in this paragraph:

* * * * *

(3) Requests for extension of the use of best available monitoring methods in 2011 for recipe-specific utilization and by-product formation rates for the plasma etching process type under § 98.93(a)(2)(ii)(A). The owner or operator may submit a request to the Administrator under this paragraph (a)(3) to use one or more best available monitoring methods to estimate emissions that occur between October 1, 2011 and December 31, 2011 for recipe-specific utilization and by-product formation rates for the etching process type under § 98.93(a)(2)(ii)(A).

(i) *Timing of request.* The extension request must be submitted to EPA no later than September 30, 2011.

* * * * *

(4) * * *

(i) *Timing of request.* The extension request must be submitted to EPA no later than September 30, 2011.

* * * * *

[FR Doc. 2011–15650 Filed 6–21–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0330; FRL–8875–9]

2-methyl-2,4-pentanediol; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 2-methyl-2,4-pentanediol (CAS Reg. No. 107–41–5) when used as an inert ingredient as a solvent in pesticide formulations 40 CFR 180.910 and 180.930 for use on crops (pre-harvest and post-harvest) and for direct application on animals without limitations. 2-methyl-2,4-pentanediol is commonly referred to as ''hexylene glycol''. The FB Sciences, Inc., 153 N. Main Street, Suite 100, Collierville, TN 38017 submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 2-methyl-2,4-pentanediol.

DATES: This regulation is effective June 22, 2011. Objections and requests for hearings must be received on or before August 22, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0330. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mark Dow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305– 5533; e-mail address: *dow.mark@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0330 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 22, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0330, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Exemption

In the **Federal Register** of June 8, 2010 (75 FR 32466) (FRL–8827–8), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 0E7693) by FB Sciences, Inc., 153 N. Main Street, Ste. 100, Collierville, TN 38017. The petition requested that 40 CFR 180.910 and 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of 2-methyl-2,4-pentanediol (CAS Reg. No.107–41–5) when used as an inert ingredient as a solvent in pesticide formulations applied to crops pre-harvest and post-harvest and to animals without limitations. That notice referenced a summary of the petition prepared by FB Sciences, Inc., the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue* * *.''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 2-methyl-2,4-pentanediol including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 2-methyl-2,4-pentanediol follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by 2-methyl-2,4-pentanediol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the

toxicity studies are discussed in this unit.

2- methyl-2,4-pentanediol (CAS Reg. No. 107–41–5) is an aliphatic alcohol also known as: Hexylene glycol; diolane; and 1,1,3-trimethyltrimethylene-diol. Non-pesticidal uses of 2-methyl-2,4-pentanediol include use as a chemical intermediate, a selective solvent in petroleum refining, a component of hydraulic fluids, a solvent for inks, as an additive to cement, textile dye vehicles, a lubricant and fuel additive, and as an ingredient in cosmetics and hair care products. The Food and Drug Administration (FDA) has approved of the use of 2-methyl-2,4-pentanediol as an indirect food additive such as in adhesives in contact with food under 21 CFR parts 175–178.

2-methyl-2,4-pentanediol is not acutely toxic to rats via the oral route of exposure. An Organization for Economic Cooperation and Development (OECD)–SIDS (2001) report indicates LD_{50} ranges from 2–4.47 g/kg. Acute dermal toxicity is low with dermal doses up to 2,000 milligrams/kilogram (mg/kg) that did not cause death (as cited in OECD–SIDS, 2001). It is irritating to the skin and eyes, but not a skin sensitizer in guinea pigs. It has low inhalation toxicity, with an LC_{50} of 160 parts per million (ppm) (0.772 mg/L), which is in excess of the saturated vapor concentration.

In a 90-day subchronic toxicity study, 2-methyl-2,4-pentanediol was administered by oral gavage to rats at dose levels of 50, 150, or 450 mg/kg/bw/day. In this study the functional observational battery, blood chemistry, hematological parameters and histopathological examinations were conducted. A functional observational battery test gave no indication of neurotoxicity. In both sexes, hyperplasia, hyperkeratosis, inflammatory cell infiltration and edema of the mucosa and submucosa of the stomach were observed starting at 150 mg/kg/day. These changes were indicative of a local irritative effect resulting from the oral gavage procedure. Hepatocellular hypertrophy with increased liver weight was observed at 450 mg/kg/day in both sexes, and in males at 150 mg/kg/day. In the absence of degenerative or necrotic changes these findings were considered to be adaptive responses. At 150 and 450 mg/kg/day, increased kidney weights and increased incidence of acidophilic globules in the tubular epithelium in males were suggestive of male rat specific alpha-2-microglobulin nephropathy, which is not considered as an effect relevant to humans. Observed changes were either fully or partially reversible over the 4-week recovery period. There were no adverse effects on the reproductive organs. No effects were observed at 50 mg/kg/day. A NOAEL of 450 mg/kg/day was determined for systemic toxicity because the effects described were either produced by irritation from the oral gavage procedure, or were considered adaptive responses. A range-finding 14-day study gave similar results.

No guideline reproduction studies were available for assessment, however, no adverse effects on reproductive organs (including testes, prostate, seminal vesicles, epididymis, ovaries, vagina, and uterus) were observed in the 90-day gavage study in which rats were administered 2-methyl-2,4-pentanediol at doses up to 450 mg/kg/day. Therefore, OECD SIDS concluded that no additional studies are required under the SIDS program regarding fertility. EPA agrees with this conclusion by the OECD.

In a developmental toxicity study, pregnant rats were administered 30, 300, or 1,000 mg/kg/bw/day of 2-methyl-2,4-pentanediol by gavage in 5 mL/kg of vehicle on gestation days (GD) 6–15. The NOAEL for maternal toxicity was 300 mg/kg/day based on a statistically significant reduction in group mean body weight gain and food consumption at 1,000 mg/kg/day. There was a marginal, non-statistically significant reduction in fetal body weight at 1,000 mg/kg/day. Marginally higher incidences of fetal variations, some of which were statistically significant (occipitals incompletely ossified, 21.6%; extra thoracolumbar ribs, 18.7%; and hyoid arch not ossified, 18%), occurred at 1,000 mg/kg/day. A delay in the normal ossification process was also observed in fetuses, but this was considered by the study authors to be related to reduced maternal body weight gain at this dose level. The NOAEL and LOAEL for maternal and fetal developmental toxicity were determined to be 300 and 1,000 mg/kg/day, respectively.

In another developmental toxicity study, pregnant rats received 500, 1,200, or 1,600 mg/kg/bw/day of 2-methyl-2,4-pentanediol by gavage in 10 mL/kg of vehicle on GD 6–17. At 1,200 and 1,600 mg/kg/day, dams had ataxia and reductions in mean weight gain and food consumption. At the 1,600 mg/kg/day, pregnant rats had mean weight loss, and one female aborted prior to the end of the study. Maternal toxicity at these levels corresponds to decreased fetal body weights and gravid uterine weights. Additionally, at 1,600 mg/kg/day, there was one abortion and one whole litter resorption. However, the number of fetal malformations, such as increased incidence of skeletal variations (delayed ossification, extra ribs), was not significantly different from controls. A maternal NOAEL of 500 mg/kg/day was determined by the Agency, and the same NOAEL was determined in the study for fetal toxicity. These results support the results of a study described in this unit and indicate that 2-methyl-2,4-pentanediol has low potential for developmental toxicity.

2-methyl-2,4-pentanediol is not genotoxic in either mammalian or non-mammalian cells ''in vitro.'' It was negative for mutagenicity in the Ames test, yeast cell assay and hamster ovary cell assay.

Ten rats and a rabbit exposed to an aerosol of 2-methyl-2,4-pentanediol at a concentration of 0.7 mg/L (about 145 ppm) for 7 hr/day for 9 days survived with mild upper respiratory irritation. No histopathological effects were reported.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

No acute endpoint of concern was identified in the available toxicity studies. The endpoint of concern for the

chronic reference dose (cRfD) was identified from the developmental toxicity study in rats. In this study, the NOAEL (500 mg/kg/day) was based on increased incidence of clinical signs, reductions in mean body weight gain and food consumption seen at the LOAEL of 1,200 mg/kg/day and above. This NOAEL was supported by the 90-day gavage toxicity study in rats (NOAEL 450 mg/kg/day; highest dose tested). There was a lower NOAEL (300 mg/kg/day) observed in the range finding study in rats based on a statistically significant reduction in group mean body weight gain and food consumption, and marginally higher incidences of fetal variations seen at the LOAEL of 1,000 mg/kg/day. The differences between the NOAELs of the range finding study and the developmental toxicity study in rats were considered due to artifacts of dose selection. An uncertainty factor 100X (10X for intraspecies variability and 10X interspecies extrapolation) was applied to the NOAEL. No additional uncertainty factor is necessary for use of the subchronic to chronic study because the effects were observed at the limit dose of 1,000 mg/kg/day and above. The FQPA factor for increased susceptibility of infant and children was reduced to 1X. Therefore, the cRfD is equal to population adjusted dose (cPAD). This endpoint and the dose was also used for dermal and inhalation exposure assessment for all exposure scenarios. Inhalation and dermal absorption was assumed to be 100%. This approach would provide a highly conservative estimate of risk via the dermal and inhalation routes of exposure.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR 2-METHYL-2,4-PENTANEDIOL FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	No acute endpoint of concern was identified in the available database.		
Chronic dietary (All populations) ..... Incidental oral short-term and intermediate term.	NOAEL = 500 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 500 mg/kg/day. cPAD = 500 mg/kg/day.	Developmental Toxicity Study—rats LOAEL = 1,200 mg/kg/day based on reduced body weights in maternal animals, reduced fetal body weights.
Dermal short and intermediate term	100% absorption via dermal and inhalation routes; LOC MOE..		
Inhalation short and intermediate term	100.		
Cancer (Oral, dermal, inhalation)	No evidence of carcinogenicity. SAR analysis negative for carcinogenic alerts. Not mutagenic in mammalian and non-mammalian mutagenicity assays.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 2-methyl-2,4-pentanediol, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 2-methyl-2,4-pentanediol in food as follows:

No acute endpoint of concern was identified in the database. Therefore, a quantitative acute dietary exposure assessment was not conducted.

i. *Chronic exposure.* In conducting the chronic dietary exposure assessments, EPA used food consumption information from the United States Department of Agriculture (USDA) [1994–1996 and 1998] Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for 2-methyl-2,4-pentanediol. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentration of active ingredient in agricultural products is generally at least 50% of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100% of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

ii. *Cancer.* Chronic and carcinogenicity studies were not available on 2-methyl-2,4-pentanediol. There is no evidence that 2-methyl-2,4-pentanediol is carcinogenic. The Agency used a qualitative structure activity relationship (SAR) database, DEREK Version 11, to determine if there were structural alerts. No structural alerts were identified. In addition, it is negative for mutagenicity in mammalian and non-mammalian mutagenicity assays. 2-methyl-2,4-pentanediol is rapidly metabolized and excreted as glucuronates. Based on weight-of-evidence and low toxicity mentioned in this unit, 2-methyl-2,4-pentanediol is not expected to be carcinogenic. Since the Agency has not identified any concerns for carcinogenicity relating to 2-methyl-2,4-pentanediol, a dietary exposure assessment to evaluate cancer risk was not performed.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for 2-methyl-2,4-pentanediol, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). No residential uses as a pesticide inert ingredient have been requested and none are expected. Although 2-methyl-2,4-pentanediol is used in cosmetics and hair care products, the Agency believes exposure and risk from these routes of exposure to be negligible. The FDA includes 2-methyl-2,4-pentanediol (*i.e.,* hexylene glycol) in its list of Indirect Additives Used in Food Contact Subtances. The exposure to 2-methyl-2,4-pentanediol through hair color use is considered minimal because it is a volatile chemical, treatment times are very short and absorption through the scalp is limited. Based on these considerations, the Agency concluded that there is no need to conduct aggregate exposure through use of consumer products. Further, there are no reliable data with which to estimate such exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found 2-methyl-2,4-pentanediol to share a common mechanism of toxicity with any other substances, and 2-methyl-2,4-pentanediol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2-methyl-2,4-pentanediol does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The maternal and developmental effects were only observed at the limit dose of 1,000 mg/kg/day and above in the developmental toxicity study in rats. Maternal and fetal toxicity were mainly manifested as decreases in body weights. Marginally higher incidences of fetal variations were also observed at the limit dose or above. There were no guideline reproduction studies available on 2-methyl-2,4-pentanediol; however, no adverse effects on reproductive organs (including testes, prostate, seminal vesicles, epididymis, ovaries, vagina, and uterus) were observed at doses up to 450 mg/kg/day in a 90-day toxicity study in rats. In addition, the reproductive indices were not affected in the two available developmental toxicity studies in rats.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for 2-methyl-2,4-pentanediol is not complete but considered as adequate for FQPA assessment given the low toxicity of 2-methyl-2,4-pentanediol. No guideline reproduction studies were available for assessment; however, no adverse effects on reproductive organs (including testes, prostate, seminal vesicles, epididymis, ovaries, vagina, and uterus) were observed in the 90-day gavage study in which rats were administered 2-methyl-2,4-pentanediol at doses up to 450 mg/kg/day. Therefore, OECD SIDS concluded that no additional studies are required under the SIDS program regarding fertility. EPA is in agreement

with the OECD conclusion. Chronic studies are also not available, but the concern for chronic toxicity is low given the low toxicity of 2-methyl-2,4-pentanediol.

ii. No evidence of clinical signs of neurotoxicity was observed in the available database. No evidence of neurobehavioral or neuropathology was seen in a 90-day toxicity study in rats. There is no indication that 2-methyl-2,4-pentanediol is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that 2-methyl-2,4-pentanediol results in increased susceptibility in rats (as described in this unit).

iv Immunotoxicity studies for 2-methyl-2,4-pentanediol were not available for review. However, there was no evidence of immunotoxicity in the available database.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 percent crop treated (PCT) and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to 2-methyl-2,4-pentanediol in drinking water. These assessments will not underestimate the exposure and risks posed by 2-methyl-2,4-pentanediol.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute (aPAD) and chronic (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, 2-methyl-2,4-pentanediol is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to 2-methyl-2,4-pentanediol from food and water will utilize 3.8% of the cPAD for the U.S. population and Children 1–2 yrs of age 12.5% cPAD, the population group receiving the greatest exposure. Based on the explanation in this unit, regarding residential use patterns, chronic residential exposure to residues of 2-methyl-2,4-pentanediol is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short-term adverse effect was identified; however, 2-methyl-2,4-pentanediol is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure resulting from use as an inert ingredient in pesticidal formulations and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for 2-methyl-2,4-pentanediol.

For the reasons discussed in Unit IV.C.3., short-term aggregate exposure assessment was not conducted for non-pesticidal uses.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, 2-methyl-2,4-pentanediol is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for 2-methyl-2,4-pentanediol. For the reasons discussed in Unit IV.C.3., intermediate term aggregate exposure assessment was not conducted for non-pesticidal uses.

5. *Aggregate cancer risk for U.S. population.* 2-methyl-2,4-pentanediol is not expected to pose a cancer risk to humans. Therefore, aggregate cancer risk was not performed.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to 2-methyl-2,4-pentanediol residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for 2-methyl-2,4-pentanediol.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 and § 180.930 for 2-methyl-2,4-pentanediol. (CAS Reg. No. 107–1–41–5) when used as an inert ingredient in pesticide formulations applied to crops and food animals without limitations.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory*

Planning and Review (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 10, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.910 Insert ingredients used pre-harvest and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
2-methyl-2,4-pentanediol (CAS Reg. No.–107–41–5)	Without limitation	Growing crops and food animals
* * * * * * *		

■ 3. In § 180.930, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.930 Insert ingredients applied to animals: exemption from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
2-methyl-2,4-pentanediol (CAS Reg. No.–107–41–5)	Without limitation	Growing crops and food animals
* * * * * * *		

[FR Doc. 2011–15466 Filed 6–21–11; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0474; FRL–8877–1]

Diethylene Glycol MonoEthyl Ether (DEGEE); Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of Diethylene Glycol MonoEthyl Ether (DEGEE) when used as an inert ingredient as a solvent, stabilizer and/or antifreeze within pesticide formulations/products, for preharvest use on growing crops and raw agricultural commodities, without limitation. Huntsman, Dow AgroSciences L.L.C., Nufarm Americas Inc., BASF, Stepan Company, Loveland Products Inc., and Rhodia Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of DEGEE on growing crops and raw agricultural commodities.

DATES: This regulation is effective June 22, 2011. Objections and requests for hearings must be received on or before August 22, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0474. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Lisa Austin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 305–7894; *e-mail address: austin.lisa@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0474 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 22, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2008–0474, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Exemption

In the **Federal Register** of July 9, 2008 (73 FR 39291) (FRL–8371–2), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 8E7355) by Huntsman, 10003 Woodloch Forest Drive, The Woodlands, TX 77380; Dow AgroSciences L.L.C., 9330 Zionsville Road, Indianapolis, Indiana 46268; Nufarm Americas Inc., 150 Harvester Drive, Suite 220, Burr Ridge, Illinois, 60527; BASF, 26 Davis Drive, Research Triangle Park, NC 27709; Stepan Company, 22 W. Frontage Road, Northfield, IL 60093; Loveland Products Inc., PO Box 1286, Greeley, CO 80632; and Rhodia Inc., CN 1500, Cranbury, New Jersey, 08512. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of DEGEE (CAS Reg. No. 111–90–0) when used as an inert ingredient, as a solvent, stabilizer and/or antifreeze